

Editorial



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Transparency in Research: What is Clinical Trial Registration and Why It Matters

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Clinical trial registration has been one of the most important developments in modern publishing and research. While the requirement for registering clinical trials has originally started as an editorial policy, today it is considered one of the most important factors in research ethics.

In 2004, the International Committee of Medical Journal Editors (ICMJE) reported that the registration of clinical trials is an essential requirement for publication (1). In their 2006 update, the ICMJE further clarified this requirement by clearly defining acceptable registries and pointing out that trials must be registered before patient enrollment begins (2). In the same year, the World Health Organization expanded these efforts globally by starting the International Clinical Trials Registry Platform to harmonize clinical trial registration worldwide (3-5). These efforts turned trial registration from a suggestion into an international requirement.

As the Turkish Archives of Otorhinolaryngology, our main goal is to maintain the highest standards of scientific quality for our journal. Considering this, we would like to, once again, draw attention to a critical requirement for ensuring that all submitted research fully comply with the ethical principles and the transparency standards: prospective clinical trial registration.

So, what is clinical trial registration? Clinical trial registration is the formal process of recording a clinical study in a publicly accessible database before or at the time of participant enrollment. It constitutes a fundamental component of ethical and methodologically strong clinical research. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome (2). Thus, any study designed to evaluate the effects of an intervention (drug, device, surgical technique, or other therapeutic approach) in human participants as a randomized controlled trial should be registered together with its protocol details.

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The main responsible authority for clinical trial registration in Türkiye is the Turkish Medicines and Medical Devices Agency (*Türkiye İlaç ve Tıbbi Cihaz Kurumu*) under the Ministry of Health. Within this agency, the clinical trials department is mainly responsible for clinical trial registration.

Registration of a clinical trial is a key part of honest and responsible research. By openly sharing their studies, researchers show that their methods are honest and take responsibility for their findings (1-3). Making the study protocol public from the beginning prevents hidden changes and selective reporting, so that the results can be trustworthy for the patients, clinicians, and the scientific community (1,2). Registration also reduces publication bias by making sure that all initiated trials are publicly documented. When trials are visible within registries, studies with negative or inconclusive results are less likely to remain unpublished. Nevertheless, evidence shows that registration alone does not fully eliminate reporting problems. Scott et al. (6) showed that discrepancies between registered and published outcomes continue to occur in journals that mandate prospective registration. These findings support the conclusion of Smith and Dworkin (7) that prospective registration is “not sufficient, but always necessary.” Similarly, Showell et al. (8) reported that a proportion of registered trials remain unpublished.

Beyond methodological considerations, clinical trial registration also protects research participants and patients and upholds the ethical principles in human research by encouraging openness and responsibility (3). We can ensure that no study, regardless of its outcome, is lost by registering all clinical trials. This provides researchers and medical professionals with the whole picture and gives them confidence that the information guiding patient care is transparent, honest, and reliable (4,5).

Registration is declared as necessary by many major organizations like the ICMJE, WAME, and COPE (1,2). The 2007 consensus statement on mandatory registration of clinical trials showed that prospective registration should be considered as both an ethical obligation and a professional responsibility in scientific publishing (9). Therefore, during submission to the Turkish Archives of Otorhinolaryngology Journal, we ask that all clinical research manuscripts include a valid trial registration number. This helps us be confident that the research we share earns the trust of doctors, researchers, and readers everywhere.

In conclusion, registration of a clinical trial is a very important and a major step in honest, responsible, and ethical scientific research. Clinical trial registration helps us keep the editorial process open and clear and make sure that the research is

done in an ethical way. We strongly encourage all authors to ensure that trial registration has been completed prior to manuscript submission.

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Footnotes

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